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SEP 28 2004

**SECTION 2 – 510(k) SUMMARY**

Passing Needle with ETHIBOND, PANACRYL or ORTHOCORD suture

**Submitter's Name and Address:**  
DePuy Mitek  
a Johnson & Johnson company  
249 Vanderbilt Avenue  
Norwood, MA 02062

**Contact Person**  
Ruth C. Forstadt  
Project Management Lead, Regulatory Affairs  
DePuy Mitek  
a Johnson & Johnson company  
249 Vanderbilt Avenue  
Norwood, MA 02062  
  
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**Name of Medical Device** Classification Name: **ETHIBOND**  
Non-absorbable poly(ethylene terephthalate) suture under 21 CFR 878.5000.  
**PANACRYL**  
Absorbable surgical suture, polydioxanone under 21 CFR 878.4493.  
**ORTHOCORD**  
PDS Suture carries an FDA product code NEW, and is classified as absorbable surgical suture, polydioxanone under 21 CFR 878.4840.  
Polyethylene sutures carries an FDA product code GAT, and is classified under 21 CFR 878.5000.

Common/Usual Name: Suture

Proprietary Name: Passing Needle with ETHIBOND, PANACRYL or ORTHOCORD suture

**Substantial Equivalence** PANACRYL sutures have been cleared by FDA - K964345; ETHIBOND sutures have been approved by FDA - NDA 17-804 & 17-809; ORTHOCORD sutures have been cleared by FDA- K040004

Premarket Notification: Traditional  
Passing Needles with ETHIBOND, PANACRYL or ORTHOCORD suture

**Confidential**

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Passing Needle with ETHIBOND, PANACRYL or ORTHOCORD suture has been cleared by the FDA – K041806.

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<b>Device Classification</b>	Sutures are Class II devices.
<b>Device Description</b>	<u>Mitek Passing Needle with ETHIBOND, PANACRYL or ORTHOCORD suture</u> is a suture and needle assembly to be used <i>in vivo</i> for suture passage through soft tissue during the surgical procedure. It is packaged with colored clips and is designed to be used with the Mitek Suture Passer. The Passing Needle with PANACRYL, ETHIBOND or ORTHOCORD suture may also be used with other Mitek anchor products.
<b>Indications for Use</b>	<u>Passing Needle with PANACRYL, ETHIBOND, or ORTHOCORD suture</u> is indicated for use in general soft tissue approximation and/or ligation in orthopedic procedures. Specifically Arthroscopic Bankart and Rotator Cuff Procedures encompassing tendon and ligament reconstruction.
<b>Safety</b>	These sutures have been cleared through K964345 (PANACRYL), NDA 17-804 & 17-809 (ETHIBOND) and K040004 (ORTHOCORD). Safety data may be referenced in these documents.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 28 2004

Ms. Ruth C. Forstadt  
Project Management Lead, Regulatory Affairs  
DePuy Mitek  
249 Vanderbilt Avenue  
Norwood, Massachusetts 02062

Re: K042233

Trade/Device Name: Passing Needle with Ethibond, Panacryl, or Orthcord suture  
Regulation Number: 21 CFR 878.4493  
Regulation Name: Polyglycolic acid suture  
Regulatory Class: II  
Product Code: GAM, NEW, GAT  
Dated: August 17, 2004  
Received: August 18, 2004

Dear Ms. Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*Miriam C. Provost*  
for  
Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

K042233

## Indications for Use

### 510(k) Number (if known):

Device Name: Passing Needle with ETHIBOND, PANACRYL or ORTHOCORD suture

### Indications For Use:

Passing Needle with ETHIBOND, PANACRYL or ORTHCORD suture is indicated for use in general soft tissue approximation and/or ligation in orthopedic procedures. Specifically Arthroscopic Bankart and Rotator Cuff Procedures encompassing tendon and ligament reconstruction..

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost  
(Division Sign-Off)  
**Division of General, Restorative,  
and Neurological Devices**

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Premarket Notification: Traditional  
Passing Needles with ETHIBOND, PANACRYL or ORTHOCORD suture